

ORBSPORT™

SMART MOUTHGUARD

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

The ORB Sport™ Smart Mouthguard ("Device") is an intraoral appliance that protects your teeth while capturing physiological and biomechanical data, including but not limited to heart rate, body movement, and calories burned.

The ORB Sport Smart Mouthguard is paired with an ORB Sport mobile app to monitor trends over time, and provide limited real-time data during an activity, allowing you to track personal fitness and performance metrics.

INDICATIONS FOR USE

The ORB Sport Smart Mouthguard is intended for use by individual athletes engaged in contact or combat sports requiring a mouthguard and who wish to track their physical performance for training and monitoring purposes.

LIMITATIONS

The Device is NOT a medical diagnostic or detection tool, and should NOT be considered efficacious in identifying injuries or other medical conditions.

Dental procedures or treatments following the impression used to customize the Device may result in the Device not providing full protection or fitting as intended.

CONTRAINDICATIONS

The Device is contraindicated for people who:

- Have severe respiratory disorders
- Have loose teeth or advanced periodontal disease
- Are currently undergoing orthodontic treatment

WARNINGS

Use of this device may cause:

- Tooth movement or changes in dental occlusion
- Gingival or dental soreness
- Pain or soreness to the temporomandibular joint
- Obstruction of oral breathing
- Excessive salivation

DATA ADVISORY

The ORB Sport mobile app, which will receive data from the mouthguard, is intended only for individuals 13 years of age or older, unless parental consent has been provided.

LIMITED WARRANTY

For limited warranty terms and conditions and limitation of liability, visit orbsport.com/warranty.

SAFETY AND HANDLING INFORMATION

Please read this information thoroughly before using the ORB Sport Smart Mouthguard and charging case. The Device contains sensitive electronic components and can be damaged if burned, punctured, or subjected to forceful impact. Do not use the Device if it is damaged or if you are allergic to EVA plastic material. Check with a dental professional about using retainers or other intraoral appliances while using the Device.

Safety:

- Do not chew on the Device as it may cause tears and damage or expose electronic components.
- Do not connect or disconnect the power cable with wet hands.
- Do not attempt to disassemble or otherwise alter the Device or charging case. Doing so will void the warranty and may create safety risks.
- The Device may present a choking hazard and should be kept away from small children.
- Keep out of reach of pets, particularly dogs, to ensure the safety of the device and your pet.

SAFETY AND HANDLING INFORMATION

Care and Cleaning:

- Store the Device in its charging case when not in use.
- Do not expose the Device or charging case to extreme temperatures (greater than 100 degrees Fahrenheit or lower than 14 degrees Fahrenheit).
- Keep the Device and charge case in a shaded, well-ventilated area when charging.
- The charging case is not waterproof. Do not use the charging case in wet locations, such as near a sink or bathtub.
- Clean the Device as instructed if it is dropped or otherwise contaminated.
- Clean with cool water only (using a soft toothbrush if necessary) and leave to air dry before charging.
- Clean the Device as instructed in the Instructions for Use. Do not use mouthwash, hand soap, sanitizers, or other similar products to clean the Device. Rinse mouth with clear water before using the Device.

Disposal:

- When the product reaches its end of life, do not dispose of the ORB Sport Smart Mouthguard with household waste. Dispose of the device and/or charging case in accordance with local environmental laws and guidelines pertaining to electrical and electronic equipment.

TROUBLESHOOTING

For any issues, please visit orbsport.com/support or call 866-499-0058.

COMPLIANCE

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

COMPLIANCE

WARNING - Unauthorized antennas, modifications, or attachments could impair call quality, damage the device, or result in violation of FCC regulations.

MPE/SAR/RF exposure information:










This device was verified and found to comply with FCC Part 1.1310 RF exposure requirements set forth for an uncontrolled environment.

This device includes a radio transmitter and receiver which is designed and manufactured not to exceed the emissions limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission (FCC). These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. These guidelines are based on the safety standards previously set by the U.S., Canada, and international standards bodies. The standards include a substantial safety margin designed to assure the safety of all persons, regardless of age and health.

The exposure standard for wireless RF devices employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6 W/kg averaged over any 1 gram of tissue. SAR values at or below that limit is considered safe for the general public. Based on the maximum available output power of less than 1mW, this device is categorically exempt from SAR as outlined in FCC Part 1.1307(3)(i) regardless of separation distance.

REFERENCE STANDARDS

1. Title 47 of the Code of Federal Regulations, Part 15, Subpart B: Unintentional Radiator (FCC 47/CFR PT 15 SPTB*AEI)
2. Title 47 of the Code of Federal Regulations, Part 15.247: Operation within the bands 902–928 MHz, 2400–2483.5 MHz, and 5725–5850 MHz (FCC 47/CFR PT 15.247*AEI)
3. Title 47 of the Code of Federal Regulations, Part 18: Industrial, Scientific, and Medical Equipment (FCC 47/CFR PT 18*AEI)
4. Audio/Video, Information & Communication Technology Equipment - Standard Requirements (UL STD 62368-1)

Symbol	Reference No. EN ISO 15223-1	Title - Symbol Description
	5.4.3	Consult Instructions for Use – Indicates the need for the user to consult the instructions for use.
	5.4.4	Caution – Indicates the user needs to consult the instructions for use for important cautionary information such as warnings and precautions.
	5.3.2	Keep away from sunlight - Indicates a medical device that needs protection from light sources.
	5.3.7	Temperature limit - Indicates the temperature limits to which the medical device can be safely exposed.
	5.2.8	Do not use if package is damaged – Indicates that the device must not be used if the package holding the device is damaged.
	5.1.1	Manufacturer- Indicates the device manufacturer.
Symbol	Reference IEC 60417	Title - Symbol Description
	6414	Waste Electrical and Electronic Equipment - Indicates that separate collection for waste electric and electronic equipment (WEEE) is required.
Symbol	Reference FCC	Title - Symbol Description
	N/A	FCC Mark - Indicates that the electromagnetic radiation from the device is below the limits specified by the Federal Communications Commission and the manufacturer has followed the requirements of the Supplier's Declaration of Conformity authorization procedures.
Symbol	Reference ETL	Title - Symbol Description
	N/A	Electrical Testing Laboratories (ETL) Certified.

ORB INNOVATIONS

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PK-4602122-091224
IFU-012636_2 (2024-09-16)
P/N: 1014562